

EPA SANITIZED

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

JM 1/6/15
1/6/15

2015 JAN -6 PM 3:19

RECEIVED
OPT/CBIC

In the matter of:

)

Microbial Commercial Activity
Notice Number:

)

)

)

)

)

Algenol Biofuels Inc.

)

J-14-0007, J-14-0008, and J-14-0009

)

)

)

)

)

Consent Order and Determinations Supporting Consent Order

TABLE OF CONTENTS

Preamble

- I. Introduction
- II. Summary of Terms of the Order
- III. Contents of MCAN
- IV. EPA's Assessment of Exposure and Risk
- V. EPA's Conclusions of Law
- VI. Information Required to Evaluate Environmental Effects

Consent Order

- I. Scope of Applicability and Exemptions
- II. Terms of Manufacture, Processing, Distribution in Commerce, Use, and Disposal Pending Submission and Evaluation of Information
- III. Recordkeeping
- IV. Requests for Pre-Inspection Information
- V. Successor Liability Upon Transfer of Consent Order
- VI. Modification and Revocation of Consent Order
- VII. Effect of Consent Order

Attachment A - Definitions

Attachment B - Notice of Transfer of Consent Order

PREAMBLE

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding microbial commercial activity notices ("MCAN") J-14-0007 for the intergeneric microorganism [REDACTED] J-14-0008 for the intergeneric microorganism [REDACTED], and J-14-0009 for the intergeneric microorganism [REDACTED] ("the MCAN microorganisms") submitted by Algenol Biofuels Inc. ("the Company"), to take effect upon expiration of the MCAN review period. The Company submitted the MCAN to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 725.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for this MCAN microorganism requires the Company to:

- (a) submit to EPA horizontal gene transfer studies to naturally transformable cyanobacteria within one year from commencement of manufacturing;
- (b) not manufacture the MCAN microorganism at any facility in the United States other than the Company's commercial development campus, including the 36 acre integrated biorefinery

facility and adjacent biological and process development facilities located at 16121 and 16161 Lee Road, Ft. Myers, FL 33912;

- (c) not manufacture the MCAN microorganism other than within the VIPER™ fully enclosed and sealed plastic photobioreactors, or equivalent, and related inoculum scale-up systems described in the MCAN ;
- (d) have in place procedures for the containment and removal/inactivation of the MCAN microorganisms in the event of environmental release;
- (e) monitor and record all releases of the MCAN microorganism greater than 10 liters resulting from a spill or leak occurring over a single batch cycle from an individual bag and document procedures used to clean-up the site of release.;
- (f) keep records of replacement/repair of photobioreactor bags and the reason for replacement/repair;
- (f) maintain certain records.

III. CONTENTS OF MCAN

By signing this Order, the Company represents that it has carefully reviewed this document and agrees that all information herein that is claimed as confidential by the Company is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

Confidential Business Information Claims (Bracketed in the Preamble and Order):

MCAN microorganisms; recipient microorganism; donor microorganisms; genetic modifications; process descriptions.

Chemical Identity:

Specific: J-14-0007 [REDACTED]

J-14-0008: [REDACTED];

J-14-0009: [REDACTED]

Generic: Enhanced algae

Use:

Specific: production of biofuels and fuel intermediates (e.g., bio-crude and bio-oil), including ethanol, biodiesel, gasoline and jet fuel

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following are EPA's predictions regarding the possible environmental effects and environmental release of the MCAN microorganism, based on the information currently available to the Agency.

As proposed in the MCAN submission, the MCAN microorganisms are contained in the

Company's VIPER™ photobioreactor system at the Company's commercial development campus with an address of 16121 Lee Road, Ft. Myers, FL 33912. There is no environmental release of the microorganism expected, or only small quantities if a photobioreactor was to leak. Therefore, the use of the submission microorganisms for ethanol production as proposed at the Ft. Myers, FL facility given proper containment poses low risk.

There are little concerns for adverse human health effects from the MCAN microorganisms as they have been shown to be devoid of the gene sequences that encode the major groups of cyanotoxins. However, it is unknown whether this cyanobacterium produces the putative neurotoxic non-protein amino acid β -N-methyl-amino alanine (BMAA) and under what conditions. However, many taxa of cyanobacteria have been shown to produce BMAA, so it is unknown how often humans already encounter this compound hypothesized by some groups to be associated with neurodegenerative diseases. Although production of high concentrations of BMAA by these MCAN microorganisms is not expected with the current manufacturing process, it needs to be demonstrated that these MCAN microorganisms do not produce significant quantities of BMAA before manufacturing moves to facilities other than the facility identified in the MCAN where production volumes are likely to increase. To the extent that no definitive link between BMAA and neurodegenerative disease has been established, a further assessment of this topic may only be necessary if the MCAN microorganisms is shown to produce BMAA in significant quantities.

Exposure to workers is also low. Estimates of exposure to the general population given releases from the facility are low assuming no, or very limited breaches of containment.

Likewise, there are low concerns for adverse ecological effects resulting from the proposed use of the three production strains for ethanol production in the photobioreactors given

proper containment. However, a process to obtain greater certainty on the environmental behavior of the recipient microorganism in the event of a large breach in containment is desirable as there is relatively little data on the recipient microorganism other than that the species to which it is phylogenetically closest to [REDACTED] used to be classified as [REDACTED]. [REDACTED] species are quite populous in the open ocean environment, but are also found ubiquitously in surface waters of freshwater, and in soils, although apparently not in desert soils. [REDACTED] species are quite important in providing oxygen on the planet through photosynthesis, and therefore, typically seen as beneficial microorganisms. The recipient microorganism is also closely related to another cyanobacterium that was formerly classified as a [REDACTED]. Members of this genus of cyanobacteria are also widespread in the environment contributing to oxygen production and carbon fixation with few adverse effects.

The genes introduced into the recipient to create the MCAN microorganisms are not inherently hazardous. The [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Although

the DNA was introduced into the recipient on various plasmids for the three strains, the conjugative mobility of those three plasmids has been diminished. Therefore, horizontal gene transfer by the mechanism of conjugation which is often the most likely mechanism of gene transfer is also expected to be low. The process of transformation, i.e., the uptake of free DNA by competent cells, would still be a possibility with dead cells. There are numerous cyanobacteria in basically all environments, some of which are naturally transformable.

Although the Company has not observed cyanophage infection with their strain during multiple years of indoor and outdoor cultivation, gene transfer by that mechanism is still a possibility. However, since the spent cyanobacterial cells are treated in a hydrothermal process to produce a bio-oil that is further transformed into other biofuels, there is no disposal of spent biomass.

The EPA believes there remains some uncertainty as to the ability of these production strains to survive in the environment if inadvertently released at the current site or at future sites. In invasiveness studies conducted by the Company with oversight from State of Florida regulatory agencies, the survival of the MCAN microorganisms was measured in several different water samples in the vicinity of the Company's facility. Water samples were obtained from a canal on the Company's site, from the Lee Road canal just outside the Company's site, from the Caloosahatchee River in Ft. Myers, from the Estero Bay where the Estero River intersects the Gulf of Mexico, and from the Gulf of Mexico off of the Ft. Myers Beach. These water samples were heavily inoculated with 10^7 cells and incubated in 1 L sterilized Schott glass bottles with bubbling of humidified air to provide the CO_2 . The bottles were incubated under 12-hr light/12-hr darkness cycles photosynthetically active radiation (PAR). The presence of the organism was assessed by polymerase chain reaction (PCR) measurement using primers specific for the MCAN microorganism. The green color within the bottles resulting from addition of the organisms disappeared within one week which may indicate death of the cells. Native algae flourished in the bottles suggesting that conditions were amenable to algal growth. No PCR sequences were detected in the Company's canal and Lee Rd. canal samples at 26 and 33 days, respectively. For the Estero Bay and Gulf of Mexico seawater, PCR signals varied more but were mostly gone by day 54, and were completely gone by day 68. The greatest survival was observed in the Caloosahatchee River sample as weak, diminishing PCR signals were still

positive through day 68 which was the final sampling date. In a second invasiveness study, slightly different results were observed. Again, survival was limited in the canal waters, but PCR signals were detected for up to 48 days in the river water. However, the best survival occurred in the Ft. Myers Beach seawater with detection up to 76 days in untreated seawater. Nutrient amendment in this water increased survival of the MCAN strain. In no case were the PCR signals higher at the end of the incubation than at the start of the cultivation. PCR technology is capable of detecting DNA remnants from lysed or non-viable cells, as well as living cells and provides a very robust indicator of any genetic material from the MCAN organism.

Although the use of the production microorganisms as proposed at the Ft. Myers, FL site may not pose unreasonable risks, the same conclusion may not be true if the microorganism was produced and released at larger scales and in other environments. If there was a catastrophic failure of containment due to a weather event such as a hurricane or a tornado, there may be concerns for effects on the surrounding ecosystem. Catastrophic failure could potentially result in disruption of algal balances in surface waters, changes in food web and trophic transfers, as well as the production of limited amounts of ethanol in the environment.

Although accelerated weathering chambers have suggested that the bioreactor bags are robust, there are still uncertainties with the prolonged integrity of the bioreactor bags and associated tubing since these systems have not been operated under actual long term environmental exposures.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

- (a) EPA is unable to determine the potential for environmental fate and effects upon environmental release of the MCAN microorganism. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the environmental effects of the MCAN microorganisms.

- (b) In light of the potential risk of environmental effects posed by the uncontrolled manufacture, processing, distribution in commerce, use, and disposal of the MCAN microorganisms, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, processing, distribution in commerce, use, and disposal of the MCAN microorganisms may present an unreasonable risk of injury to the environment.

VI. INFORMATION REQUIRED TO EVALUATE

ENVIRONMENTAL EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding a specified production limit unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

Pended Testing. The following additional information would be required to evaluate the human health and environmental effects of the MCAN microorganisms:

- (a) determination of whether the MCAN microorganisms produce β -N-methyl-amino alanine (BMAA);
- (b) conduct additional rigorous testing of the ability of the microorganisms to survive in representative waters and soils for any future manufacturing facility using a technique for enumeration of viable cells in conjunction with detection of PCR signals;
- (c) confirm efficacy of inactivation methods used prior to discarding the biomass as waste.

The Order does not require submission of the above pended testing at any specified time or production volume. However, the Order's restrictions on manufacture (defined by statute to include import), use, and disposal of the MCAN microorganism will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

EPA SANITIZED

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the intergeneric microorganisms [REDACTED] [REDACTED] (J-14-0007), [REDACTED] (J-14-0008] and [REDACTED] (J-14-0009) ("the MCAN microorganisms") in the United States by Algenol Biofuels Inc. ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the MCAN microorganisms is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Company begins commercial manufacture of the MCAN microorganism for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the MCAN microorganism solely for export in accordance with TSCA §§12(a) and 12(b), 40 CFR 725.920(a) and 40 CFR Part 707. However, once the Company begins to manufacture the MCAN microorganism for use in the United States, no further activity by the Company involving the MCAN microorganism is exempt

as "solely for export" even if some amount of the MCAN microorganism is later exported. At that point, the requirements of this Order apply to all activities associated with the MCAN microorganism while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the MCAN microorganism that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order

(2) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the MCAN microorganism in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 725.110(a), 40 CFR 725.232 and 40 CFR 725.234.

**II. TERMS OF MANUFACTURE (INCLUDING IMPORT), PROCESSING,
DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL
PENDING SUBMISSION AND EVALUATION
OF INFORMATION**

PROHIBITION

The Company is prohibited from manufacturing (defined by statute to include import), processing, distributing in commerce, using, or disposing of the MCAN microorganisms in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the microorganisms, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

TESTING

(a) Section 8(e) Reporting. Reports of information on the MCAN microorganisms which reasonably supports the conclusion that the MCAN microorganisms present a substantial risk of injury to health or the environment and which is required to be reported under TSCA section 8(e) shall reference the appropriate MCAN identification number for this microorganism and contain a statement that the microorganism is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found at www.epa.gov/oppt/tscas8e.

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Monitoring Assistance and Media Programs Division (2227A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

- (1) The date when the study is scheduled to commence;
- (2) The name and address of the laboratory which will conduct the study;
- (3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,
- (4) The appropriate MCAN identification number for each microorganism and a statement that the microorganism is subject to this Consent Order.

The written notice should be submitted to EPA as follows:

Postal Mail Address

U.S. Environmental Protection Agency

GLP Section Chief – Pesticides, Water and Toxics Branch
Monitoring Assistance and Media Programs Division (2227A)
Office of Enforcement and Compliance Assurance
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Courier Delivery Address

U.S. Environmental Protection Agency
GLP Section Chief – Pesticides, Water and Toxics Branch
Monitoring Assistance and Media Programs Division (2227A)
Office of Enforcement and Compliance Assurance
Room 7117B
1200 Pennsylvania Avenue, N.W.
Washington, DC 20004

(c) Good Laboratory Practice Standards and Test Protocols. Each study performed to address the risks identified in this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any study that will use a modified version of a published test guideline, the Company must submit written test protocols to EPA for review (submission of written test protocols is optional for tests that are to be

conducted using unmodified published test guidelines). Protocols must be submitted as a support document for the MCAN, using the procedures set out in 40 CFR 720.40. EPA will respond to the Company within 4 weeks of receiving the written protocols. EPA review of a test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. The Company is prohibited from manufacturing (defined by statute to include import) the MCAN microorganisms after a certain date ("the production limit"), unless the Company conducts the following studies on the MCAN microorganisms and submits all final reports and underlying data in accordance with the conditions specified in this Testing section.

<u>Production Limit</u>	<u>Study</u>
One year from commencement of manufacturing of the MCAN microorganisms	Horizontal gene transfer studies to naturally transformable cyanobacteria

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit the final report of each study (with an additional sanitized copy, if confidential business information is involved) and all underlying data ("the report and data") to EPA prior to exceeding the applicable production limit. The final report and data must be submitted as a support document for the MCAN, using the procedures set out in 40 CFR 725.25. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test

Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture (defined by statute to include import) the MCAN microorganisms beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e) (except that the study may be submitted after reaching the applicable production limit). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the MCAN microorganisms, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by

a study are scientifically invalid, the Company is prohibited from further manufacture (defined by statute to include import) of the MCAN microorganisms beyond the applicable production limit.

(2) The Company may continue to manufacture (defined by statute to include import) the MCAN microorganisms beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) If there is sufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may reconduct the study. If there is insufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c), and (e), and shall submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c)

and (e), the Company remains prohibited from further manufacture (defined by statute to include import) of the MCAN microorganisms beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture (defined by statute to include import) the MCAN microorganisms beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e), if there is sufficient time to conduct or reconduct the study and submit the report and data to EPA before exceeding the production limit specified in paragraph (d). If there is insufficient time for the Company to comply with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c), and (e), and shall submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture (defined by statute to include import) beyond the applicable production limit.

(j) Unreasonable Risk.

EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the

MCAN microorganisms will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture (defined by statute to include import), processing, distribution, use and/or disposal of the MCAN microorganisms to mitigate exposures to or to better characterize the risks presented by the MCAN microorganisms. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture (defined by statute to include import), processing, distribution, use and disposal of the MCAN microorganisms, unless either:

(1) within 2 weeks from receipt of the EPA notice, the Company complies with such requirements as the notice specifies; or

(2) within 4 weeks from receipt of the EPA notice, the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture (defined by statute to include import), process, distribute, use and dispose of the MCAN microorganisms in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture (defined by statute to include import), processing, distribution, use and disposal of the MCAN microorganisms.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant

information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI. of this Consent Order.

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture (defined by statute to include import) of the MCAN microorganisms by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the MCAN microorganisms under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the MCAN microorganisms and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture (defined by statute to include import) the MCAN microorganisms of the existence of the SNUR.

(b) The Company shall not manufacture the MCAN microorganism at any facility in the United States other than the Company's commercial development campus, including the 36 acre integrated biorefinery facility and adjacent biological and process development facilities located at 16121 and 16161 Lee Road, Ft. Myers, FL 33912;

(c) The Company shall not manufacture the MCAN microorganisms other than within the VIPER™ fully enclosed and sealed plastic photobioreactors, or equivalent, and related inoculums scale-up systems described in the MCAN;

(d) In the event of environmental release of the MCAN microorganisms, the company must have in place procedures for the containment and removal/inactivation of the MCAN microorganisms.

(e) The Company must monitor for and record all releases of the MCAN microorganism (greater than 10 liters resulting from a spill or leak occurring over a single batch cycle from an individual bag) and document procedures used to clean-up the site of release. This would include, but not be limited to:

- (1) Breaches in photobioreactor integrity;
- (2) accidental spills;
- (3) catastrophic failures of photobioreactors due to weather or other environmental conditions;

(f) The Company must keep records of replacement/repair of photobioreactor bags and the reason for replacement/repair.

USE

(a) The Company may only use the MCAN microorganisms for the production of ethanol and as site-limited intermediate (e.g. bio-crude or bio-oil) for the production of biofuels as described in the MCAN.

DISTRIBUTION

(a) Export Notice Requirement. No later than the date of distribution, the Company shall notify in writing any person to whom it distributes the MCAN microorganisms that, due to the issuance of this Consent Order under section 5(e) of TSCA, the MCAN microorganisms are subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the MCAN number, and (2) either (A) the specific chemical identity of the MCAN microorganisms, or (B) if the specific chemical identity is confidential, the generic chemical identity.

DISPOSAL

In the event that it is necessary for the Company to dispose of the MCAN microorganism as waste, the Company shall dispose of the MCAN microorganisms and any waste stream containing the MCAN microorganisms only as follows. This provision does not supersede or preempt any applicable federal, state, and local laws and regulations if those laws are more stringent than the requirements below.

(1) If not used as a site-limited intermediate (e.g. bio-crude or bio-oil) for the production of biofuels, the MCAN microorganisms, prior to disposal, must be inactivated via a method deemed adequate by the EPA and must be disposed of only by:

- (i) incineration;
- (ii) landfill;
- (iii) deep well injection.

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the MCAN microorganisms did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the MCAN microorganisms eligible for the export only exemption in Section I, Paragraph (b)(1) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the MCAN microorganisms eligible for the research and development exemption in Section I, Paragraph (b)(2) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the MCAN microorganisms claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture (defined by statute to include import) volume of the MCAN microorganisms and the corresponding dates of manufacture (defined by statute to include import);

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture (defined by statute to include import) to whom the Company directly sells or transfers the MCAN microorganisms, the date of each sale or transfer, and the quantity of the microorganism sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture (defined by statute to include import), processing, and use;

(5) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(6) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of MCAN microorganisms disposed. Where the estimated disposal volume is not known to the Company and is not reasonably ascertainable by the Company, the Company must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements;

(7) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and,

(8) The Company shall keep a copy of this Order at each of its sites where the MCAN microorganisms are manufactured (defined by statute to include import).

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the MCAN microorganisms. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

(1) Expected dates and times when the MCAN microorganisms will be in production within the subsequent 12 months;

(2) Current workshift schedules for workers who are involved in activities associated with the MCAN microorganisms and may reasonably be exposed to the MCAN microorganisms;

- (3) Current job titles or categories for workers who are involved in activities associated with the MCAN microorganisms and may reasonably be exposed to the MCAN microorganisms;
- (4) Existing exposure monitoring data for workers who are involved in activities associated with the MCAN microorganisms and may reasonably be exposed to the MCAN microorganisms;
- (5) Records required by the Recordkeeping section of this Order; and/or,
- (6) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable by the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the MCAN

microorganisms, including the right to manufacture the MCAN microorganisms, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC.

Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture ("NOC") for the MCAN microorganisms from the Company pursuant to 40 CFR 725.1(d), the Successor in Interest must submit a new MCAN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 725 before commencing manufacture of the MCAN microorganisms.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new MCAN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the MCAN microorganisms, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the MCAN microorganisms, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the MCAN microorganisms. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3) and 40 CFR 720.3(z).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the MCAN microorganisms, including the right to manufacture the MCAN microorganisms, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to:

The written notice should be submitted to EPA as follows:

Postal Mail Address

U.S. Environmental Protection Agency
New Chemicals Management Branch (7405M)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Courier Delivery Address

U.S. Environmental Protection Agency
New Chemicals Management Branch (7405M)
1201 Constitution Avenue, N.W.
Washington, D.C. 20004

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the MCAN microorganisms is manufactured (defined by statute to include import). Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the MCAN microorganisms under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the MCAN microorganisms pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the MCAN microorganisms manufactured

(defined by statute to include import) by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the human health or environmental effects of, or human exposure to or environmental release of, the MCAN microorganisms, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the MCAN microorganisms and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the MCAN microorganisms.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

(b) CBI Brackets. By signing this Order, the Company represents that it has carefully reviewed this document and hereby agrees that all information herein that is claimed as confidential by the Company (per section 14 of TSCA, 40 CFR Part 720 Subpart E, and 40 CFR Part 2) is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

10 Dec 2014

Date

Maria J. Doa

Maria J. Doa, Ph.D., Director
Chemical Control Division
Office of Pollution Prevention and Toxics

December 12, 2014

Date

Paul Woods

Name: PAUL WOODS
Title: CEO

Company: Algenol

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture (defined by statute to include import) the MCAN microorganisms under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MCAN microorganism" means the microorganism described in the Microbial Commercial Activities Notification submitted by the Company relevant to this Order.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured (defined by statute to include import) or processed.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-reviewed protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency review that prevents a reasoned evaluation of the health or environmental effects of the MCAN microorganism.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-reviewed protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the MCAN microorganism.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the MCAN microorganism, and from which there will be no human exposure to, nor environmental release of, the MCAN microorganism during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the MCAN microorganism is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

**NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER**

Company (Transferor)

MCAN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a microbial commercial activity notice ("MCAN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act ("TSCA," 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the MCAN microorganism, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

____ reasserts,

____ relinquishes, or

____ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the MCAN microorganism(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

**NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER**

(continued)

Company (Transferor)

MCAN Number

Signature of Authorized Official

Date

Printed Name of Authorized Official

Title of Authorized Official

Successor in Interest

Signature of Authorized Official

Date

Printed Name of Authorized Official

Title of Authorized Official

Address

City, State, Zip Code

**NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER
(continued)**

Successor's Technical Contact

Address

City, State, Zip Code

Phone